## II. Remarks

Responsive to the Office Action mailed July 9, 2009, the present paper is timely filed on or before October 9, 2009. By the present paper, claim 1 is cancelled without prejudice or disclaimer of subject matter therein, claims 2 and 32 - 35 are amended, and new claim 36 is presented. Claims 2 - 14, 16 - 26, and 31 - 36 are under examination.

Entry of the claim amendments, entry of the new claim, and reconsideration of the Application are respectfully requested.

### A. The New Claims

New claim 36 replaces claim 1 to point out with even greater particularity that which Applicants consider as their invention, presenting the same subject matter in a format conforming even more closely to United States practice. Claim 36 introduces a further limitation to the viscosity of the emulsion formulations. Applicants respectfully submit that support for the viscosity limitation in new claim 36 can be found in the specification at, for example, Paragraph [0069]. Applicants further respectfully submit that new claim 36 does not introduce new matter into the Application.

### B. The Claim Amendments

Claims 2 and 33 - 35 are amended to correct their dependency required by cancellation of claim 1.

Claim 3 is amended to recite specific polymeric delivery systems. Support for the polymeric delivery systems recited in (c) and (e) can be found in Paragraph [0053] as well as Paragraph [0054], which incorporates by reference the description of polymeric delivery systems in U.S. Patent No. 5,955,109. The '109 Patent, in turn, describes suspension polymerization at Col. 3, line 65 – Col. 4, line 49. The use of methyl methacrylate and ethylene glycol dimethacrylate as starting monomers to form a polymeric delivery system as claimed in the instant invention is further described in claim 6 of the '109 Patent. Likewise, the use of styrene and divinylbenzene as the starting monomers to form a polymeric delivery system as claimed in the instant invention is described in claim 5 of the '109 Patent.

Claim 32 is amended to limit the viscosity to about 10,000 cps. Support for the amendment can be found in the specification at, for example, Paragraph [0069].

Applicants respectfully submit that the claim amendment do not introduce new matter into the Application.

**B. The Pending Claims Comply With 35 U.S.C. § 112**

Claims 1 - 14, 16 - 26, and 31 - 35 were rejected under 35 U.S.C. § 112 ¶ 1 for alleged lack of written description. More particularly, it is alleged that the phrase "less than about 25,000" is not supported in the specification. Applicants respectfully submit that cancellation of claim 1 moots the rejection and that inclusion of a lower limit in new claim 36 cures any such defect that may have existed.

Claims 1 - 14, 16 - 26, and 31 - 35 were rejected under 35 U.S.C. § 112, ¶ 2 because the phrase "less than about 25,000" is allegedly indefinite. Applicants respectfully submit that cancellation of claim 1 moots the rejection and that inclusion of a lower limit for viscosity in new claim 36 cures any such defect that may have existed.

**C. The Pending Claims Are Not Obvious 35 U.S.C. § 103**

Claims 1 - 14, 16 - 16, and 31 - 35 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Manetta *et al.*, International Patent Publication WO 01/91726 (WO '726) in view of U.S. Patent No. 7,060,732 (Vishnupad) and U.S. Patent No. 5,955,109 (Won), or in the alternative, as obvious over WO '726 in view of Vishnupad and Katz *et al.*, European Patent Application Publication 0 306 236 (EP '236). Because the Office ignores an express limitation of Applicants' claims that discloses an essential feature of Applicants' claimed invention, Applicants respectfully traverse.

Applicants turn first to the rejection over WO '726 in view of Vishnupad and Won.

WO '726 discloses a two component, acne-treating composition in which each component is stored in and dispensed from separate storage compartments within a dispensing package. When dispensed, the components are capable of forming the intended acne-treating pharmaceutical composition. *See* WO '726 at page 23, line 1. One component can include antibacterial such as BPO as an active ingredient. The other component can include an antibiotic such as clindamycin as the active ingredient. The components are stored separately because the stability of the individual components and the efficacy of the ultimate pharmaceutical composition (combination of the two components) may be compromised if they are stored together.

The description of the component compositions in WO '726 is limited – the final composition is taught to be of sufficient viscosity to adhere to the skin for sufficient time to be therapeutically effective. *See* WO '726 at page 23, lines 10-12. WO '726 does not, however, teach or suggest that the active ingredients are contained (i.e., entrapped) within a polymeric delivery system (as that term is use in Applicants' claims). Equally, if not more importantly, WO '726 is silent concerning any requirement for the lipophilicity of the components.

Vishnupad likewise discloses a "dual [chambered] dispenser" in which components of an acne-treating composition are separately stored. Vishnupad discloses that it is strongly preferred that one of the components ("compositions") is substantially anhydrous. Compositions claimed in Vishnupad are not substantially anhydrous.

Moreover, Vishnupad neither teaches nor suggests use of a polymeric delivery system (as that term is used in Applicants' claims) and Vishnupad is silent regarding the lipophilicity of the compositions used in the delivery systems therein disclosed.

Won discloses controlled-release compositions for topical delivery of retinoic acid. More particularly, the retinoic acid is retained within the pores of porous solid particles or microspheres. These porous polymeric microbead carriers (retaining the retinoic acid) may be used alone or incorporated as a dispersion in a "suitable vehicle". *See* Won, Col. 2, lines 41 – 45. Won is silent concerning the lipohilicity of the "suitable vehicle" therein disclosed.

Applicants' claims expressly require that the carriers of the first and second emulsion formulations have substantially the same lipophilicity.

In Paragraph [0018], Applicants' specification recites:

> The requirement for the formulations to comprise carrier bases with substantially the same lipophilicity is also an important feature of the invention which may facilitate particularly ready, uniform and is thermodynamically favorable mixing of the formulations. More importantly, it ensures consistent release of active ingredient from the polymeric delivery system or systems. The release properties of such systems are dependent on the physical properties of the carrier in which they are dispersed, including pH and viscosity; thus, the degree of lipophilicity is particularly important since it affects the partition coefficient of active ingredient between the polymer

> particles of the delivery system and the carrier and thus controls the rate of release of active ingredient from the particles into the carrier and thus to the skin. By using carriers with substantially identical lipophilicity the products may be designed to ensure that a desired rate of release from the polymeric delivery system is consistently achieved after the formulations have been mixed and applied to the skin. (emphasis supplied)

Controlling the rate of release of the active ingredients (and, therefore their partition coefficients into the vehicle) is key to this invention since it provides both for extended efficacy as well as reduces the potential irritancy of the final product. Thus, the limitation that the emulsion formulations of Applicants' inventive pharmaceutical and/ or cosmetic product have carriers that have substantially the same lipophilicity, as that term is used and clearly described in the specification, is an essential feature of Applicants' invention as claimed.

Applicants acknowledge that the Office is charged with construing claims as broadly as reasonably possible. But this charge is not a license to completely write an express limitation out of a claim. All words of a claim must be considered in judging the patentability of a claim against the prior art. M.P.E.P.§ 2143.03. An obviousness determination requires "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *See, In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (underscore supplied). *Accord*, *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974))("obviousness requires a suggestion of all limitations in a claim.").

Applicants' claims include the express limitation "the water-based carrier bases of the first and second emulsion formulations having substantially the same lipophilicity". The language from the specification quoted *supra* clearly establishes the essential nature of this limitation. However, the Office fails to consider, let alone accord the due patentable weight to, this express claim language.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reasons why the claimed invention would have been obvious. M.P.E.P. § 2142 (underscore supplied). The Office has not proffered any explanation as to why the claimed invention that includes the limitation to "substantially the same lipophilicity" would have been obvious to the skilled artisan of the day.

For at least the forgoing reasons, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Applicants turn next to the rejection over WO '726 in view of Vishnupad, Won, and EP '236.

Applicants here restate *ipsis verbis* their grounds for traversal of the rejection over WO '726 in view of Vishnupad and Won, and respectfully submit that even assuming, *arguendo*, that motivation *were* found to combine EP '236, the combination is at most cumulative.

EP '236 discloses incorporating active substances (e.g. retinoids) for topical administration as "impregnates" in solid porous particles or microspheres. These particles are used alone or in a dispersion in a "suitable vehicle". EP '236 at page 6, lines 1 – 5. EP '236, like the other references discussed above, is silent concerning the lipophilicity of the vehicle. EP '236 adds nothing to the obviousness analysis and Applicants respectfully submit that the rejection is improper and should be withdrawn.

**Conclusion**

Applicants have previously argued that the Office has not identified any motivation to use "microsponges" (or other similar polymeric delivery systems) in a "gel" formulation as taught by WO '726 and, therefore, incorporate in their entirety Applicants' arguments from their prior responses.

Moreover, even if there *were* motivation to combine references as argued by the Office, a conclusion to which Applicants take vigorous exception, the Office has impermissibly ignored a limitation to an essential feature of Applicants' invention recited in the claims.

Based on the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited, in particular given the advanced age of one of the inventors who is over 70 years old. If, in the view of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to telephone the undersigned attorney.

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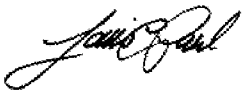
Respectfully submitted,



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